IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE TRAVELERS INDEMNITY COMPANY, et al.	:	CIVIL ACTION
v.	:	
CEPHALON, INC., et al.	:	NO. 12-4191

MEMORANDUM

McLaughlin, J. July 14, 2014

This is a fraud and unjust enrichment case brought by The Travelers Indemnity Company, Travelers Casualty & Surety Company, St. Paul Fire & Marine Insurance Company, and the Standard Fire Insurance Company (collectively, the plaintiffs, or "Travelers") against Cephalon, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. The plaintiffs are workers' compensation insurers who claim that they were injured because they paid for or reimbursed prescriptions for Actiq and Fentora, two pain-management medications owned by the defendants. The plaintiffs allege that these drugs were ineffective, unnecessary, unsafe, or otherwise inappropriate as prescribed, and that the prescriptions were written as a result of Cephalon's fraudulent marketing of the two drugs for "off-label" uses.

The plaintiffs bring claims against Cephalon for intentional misrepresentation (Count 1), negligent

misrepresentation (Count 2), and for violations of the unfair trade and consumer protection laws of multiple states (Count 5). Against all three defendants, the plaintiffs bring a claim for unjust enrichment (Count 3), and seek a mandatory injunction compelling the defendants to advise the prescribers to whom they marketed Actiq and Fentora that the use of the drugs for opioid non-tolerant non-cancer patients is inappropriate and highly dangerous (Count 4).[1]

The defendants now move to dismiss the Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1), on the grounds that the plaintiffs have failed to plead the injury or causation necessary to establish standing, and pursuant to Federal Rule of Civil Procedure 12(b)(6), for failure to state any of the remaining claims.

[1] The plaintiffs' original complaint was filed on July 24, 2012. The defendant moved to dismiss or stay the action pursuant to Federal Rule of Civil Procedure 12(b) and the first-filed rule, or to transfer the action to the District Court for the Southern District of New York, based on the earlier filing of a declaratory judgment action in that court regarding the matters in dispute in this case. The defendants' motion to transfer was rendered moot by the dismissal of the S.D.N.Y. declaratory judgment action. Subsequently, this Court granted leave for the plaintiffs to file an amended complaint (Docket No. 34), which is the subject of this memorandum. The Court notes that the plaintiffs have had the benefit of substantial discovery in filing their Amended Complaint. Hr'g Tr. at 29-30, 39, Mar. 14, 2014.

Because the Court finds that the plaintiffs have not pleaded any injury sufficient to establish Article III standing, the Court will grant the motion to dismiss under Rule 12(b)(1). In addition, the Court finds that the plaintiffs have not pleaded their claims for fraud or negligent misrepresentation with the particularity required under Federal Rule of Civil Procedure 9(b), or under the lesser standard of Rule 8. The Court also finds that the plaintiffs have not pleaded ascertainable loss or injury necessary to sustain their state consumer protection claims. Finally, the Court finds that the plaintiffs have not pleaded circumstances which would justify recovery under an unjust enrichment theory, or pleaded the type of injury required to seek relief in the form of a mandatory injunction. Accordingly, the Court will also dismiss all counts in the Amended Complaint for failure to state a claim under Rule 12(b)(6).

I. Background[2]

Actiq is a powerful painkiller which was approved by the Food and Drug Administration ("FDA") in 1998 for managing breakthrough pain in cancer patients who were already receiving

[2] The factual background set forth in this section is based on the allegations in the Amended Complaint.

and tolerant to other opioid pain therapies.[3] The 1998 FDA-approved product label provided, in part:

> Actiq is indicated only for the management of breakthrough[4] cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*. . . . . Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, Actiq is contraindicated in the management of acute or postoperative pain. This product *must not* be used in opioid non-tolerant patients.[5] . . . . Actiq is intended to be used only in the care of cancer patients only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer.

Compl. ¶ 43 (emphasis in original).

As part of its approval of Actiq in 1998, the FDA implemented a Risk Management Program ("RPM") which required

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[3] Cephalon acquired the rights to Actiq from Anesta Corporation following its merger with Anesta in or around October 2000. Compl. ¶ 49. Cephalon acquired the rights to Fentora from Cima Labs, and sought approval from the FDA for Fentora in August 2005. Compl. ¶ 110. Teva Ltd. acquired Cephalon in 2011. Compl. ¶ 148.

[4] Breakthrough cancer pain is "a transient flare of moderate-to-severe pain occurring in cancer patients experiencing persistent cancer pain otherwise controlled with maintenance doses of opioid medications." Compl. ¶ 46.

[5] A key ingredient of Actiq and Fentora is fentanyl, which depresses respiration and may lead to severe side effects or fatal respiratory complications, especially in patients who have not taken opioids before. Compl. ¶¶ 45, 112. A use is "contraindicated" when "the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit." 21 C.F.R. § 201.57(c)(5).

Cephalon to monitor prescription patterns and report to the appropriate medical professional society any doctors Cephalon identified as having prescribed Actiq inappropriately, if those prescriptions "represent potential off-label usage greater than 15% of total quarterly Actiq prescriptions."[6] Compl. ¶¶ 49-54. Additionally, if off-label usage continued to exceed fifteen percent, Cephalon would be required to implement an "aggressive education program" notifying and reminding doctors of the drug's FDA-approved uses and appropriate patient selection. Id.

Fentora poses similar dangers for addiction and fatal overdose, and its FDA-approved label includes a very detailed Black Box Warning cautioning, in part, that deaths have occurred "as a result of improper patient selections (e.g.[,] use in opioid non-tolerant patients) and/or improper dosing," that Fentora is indicated only for the management of breakthrough pain in opioid-tolerant cancer patients, and that Fentora is "contraindicated in the management of acute or postoperative pain including headache/migraine." Compl. ¶ 112.

The plaintiffs allege that, despite these dangers and FDA-imposed restrictions, beginning around October 2000 and

[6] "Off-label" uses of a drug may treating a condition not indicated on the FDA-approved label, treating the indicated condition at a different dose or frequency than that approved, or treating a different type of patient than those for whom the drug was approved. Compl. ¶ 16.

continuing to the present, Cephalon aggressively marketed, promoted, and sold both Actiq and Fentora to doctors for off-label use. In particular, Cephalon promoted the drugs to doctors treating injured workers whose medical expenses were paid for by the plaintiffs and other third-party payors ("TPPs") under state workers' compensation laws. The plaintiffs argue that Cephalon targeted these doctors because patients covered by workers' compensation enjoy full prescription reimbursement, and because state laws limit the ability of workers' compensation insurers to restrict the drugs they will cover. Compl. ¶¶ 74-76.

The plaintiffs allege that Cephalon sought to increase profits by expanding the use of Actiq and Fentora beyond their FDA-approved indications by aggressively promoting the drugs to non-cancer doctors for the treatment of non-cancer patients. Cephalon's promotion allegedly included promulgating false or misleading marketing and medical education materials, training its sales representatives to downplay the risks of the drugs for off-label use, providing doctors with free samples of or coupons for the drugs, offering doctors various financial benefits (such as paid speaking engagements) as incentives to prescribe the drugs, and reducing the prices of Actiq and Fentora to compete with generic rapid-onset opioids. The plaintiffs assert that

this marketing campaign "goes beyond mere off-label promotion of Actiq [and Fentora] and includes untruthful, factually inaccurate, incomplete and/or otherwise misleading promotion of the drug[s], and the promotion of Actiq [and Fentora] for contraindicated uses." Compl. ¶ 80.

The plaintiffs allege that between 2004 and 2011, Travelers and its customers paid at least $15 million for more than 8,400 Actiq prescriptions, submitted by more than 500 workers' compensation claimants, and paid at least $4.5 million for Fentora prescriptions from 2006 to the present. Compl. ¶¶ 97-98, 140. By way of example, the Amended Complaint identifies seven patients to whom Actiq was prescribed for pain related to back and shoulder injuries, and five patients who received prescriptions of Fentora for non-cancer-related pain, between 2006 and 2013. Compl. ¶¶ 99, 129.

The plaintiffs do not allege that they themselves heard or relied on any fraudulent statement or misrepresentation by Cephalon in choosing to pay for Actiq and Fentora. Instead, they allege that Cephalon "targeted" TPPs by directing its off-label promotion scheme at the doctors treating patients/claimants whose expenses would be reimbursed by the plaintiffs. The Amended Complaint identifies five doctors who received some form "payments/benefits" from Cephalon between

2009 and 2012, who also prescribed Fentora to Travelers' workers' compensation claimants. Compl. ¶ 162. The Amended Complaint does not, however, specifically allege that those five doctors were exposed to Cephalon's misleading marketing materials, or relied on any false statement is choosing to prescribe the drugs. The Amended Complaint does not identify any Actiq prescribers who received payments or benefits from Cephalon; however, it does identify one patient who received two Actiq prescriptions in 2006 from a doctor to whom Cephalon allegedly actively promoted the drug through informational "field rides" with sales representatives. Compl. ¶ 94.

II. Analysis

A. Off-Label Prescribing & Promotion

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq., governs the manufacturing and sale of prescription drugs, and provides that a drug cannot be introduced into interstate commerce until it is approved by the FDA for a specific use, or "indication." See In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 239 (3d Cir. 2012) ("Schering III") (citing 21 U.S.C. § 355(a)). The FDA also approves the labeling of the drug, which lists the indications which have been FDA-approved. 21 U.S.C. §

355(b)(1). If the labeling, advertising, or promotion of a drug is "false or misleading in any particular," a drug is considered "misbranded." 21 U.S.C. § 352. The FDCA and FDA regulations generally prohibit manufacturers from marketing, advertising, or otherwise promoting drugs for unapproved or "off-label" uses. See 21 U.S.C. § 331(a) and (d) (prohibiting manufacturers from introducing misbranded or unapproved drugs into interstate commerce). See also, e.g., 21 C.F.R. §§ 202.1(e)(4)(i)(a) ("An advertisement for a prescription drug . . . shall not recommend or suggest any use that is not in the labeling accepted in [the] approved new-drug application . . . ."). [7] However, because the FDCA does not regulate the practice of medicine, and because prescription drugs may have therapeutic uses other than their FDA-approved indications, physicians may lawfully prescribe drugs for off-label use. Schering III, 678 F.3d at 240 (citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350-51 (2001)).

Where off-label promotion violates the FDCA, it is subject to federal regulatory action by the FDA, or enforcement

[7] The FDCA prohibits manufacturers from directly advertising off-label uses through labeling claims or explicit statements by sales representatives. In certain limited circumstances, however, manufacturers may distribute information about off-label uses. See Schering III, 678 F.3d at 240 (citing Wash. Legal Found. v. Henney, 202 F.3d 331, 333 (D.C. Cir. 2000).

actions by the Department of Justice, but violations of the FDCA do not create private rights of action.[8] Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir. 1994).

B. Motion to Dismiss for Lack of Standing

A federal court must dismiss a complaint for lack of subject matter jurisdiction under the case-or-controversy requirement of Article III of the United States Constitution if the plaintiff lacks standing to bring a claim. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). A plaintiff bears the burden of meeting the "irreducible constitutional minimum" of Article III standing by establishing three elements:

> First, the plaintiff must have suffered an "injury in fact" – an invasion of a legally protected interest which is (a) concrete and particularized; and (b) "actual or imminent, not 'conjectural' or 'hypothetical'." Second, there must be a causal connection between the injury and the conduct complained of – the injury has to be "fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." Third, it must be "likely," as opposed to merely "speculative,"

[8] In 2008, Cephalon pleaded guilty to a violation of the FDCA, paid substantial fines, and reached settlements with various states' attorneys general related to off-label marketing of Actiq, Pro-Vigil, and Gabitril between 2001 and 2006. Compl. ¶¶ 90-91. The plaintiffs argue that these criminal investigations and settlements lend plausibility to their allegations of fraud and negligent misrepresentation. However, because a violation of the FDCA requires only prohibited off-label marketing, not fraudulent or deceptive conduct, this factual background is of limited value in alleging fraud.

> that the injury will be "redressed by a favorable decision."

Lujan, 504 U.S. at 560–61 (internal citations omitted) (explaining that "particularized" means that the injury must affect the plaintiff in a personal and individual way).

"A motion to dismiss for want of standing is . . . properly brought pursuant to [Federal] Rule [of Civil Procedure] 12(b)(1), because standing is a jurisdictional matter." Ballentine v. United States, 486 F.3d 806, 810 (3d Cir. 2007). "In evaluating a Rule 12(b)(1) motion, a court must first determine whether the movant presents a facial or factual attack." Schering III, 678 F.3d at 243 (citing Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977)). Here, the defendants' 12(b)(1) motion is properly understood as a facial attack, because the defendants contend that the Amended Complaint lacks sufficient factual allegations to establish standing. Id. In reviewing a facial challenge, a court takes the facts in the pleadings as true, construed in the light most favorable to the plaintiff, and determines therefrom whether jurisdiction exists. Gould Elecs. Inc. v. United States, 220 F.3d 169, 176 (3d Cir. 2000) (holding modified by Simon v. United States, 341 F.3d 193, 196 (3d Cir. 2003)).

"In evaluating whether a complaint adequately pleads the elements of standing, courts apply the standard of reviewing a complaint pursuant to a Rule 12(b)(6) motion to dismiss for failure to state a claim . . . ." Schering III, 678 F.3d at 243 (citing Ballentine, 486 F.3d at 810). See also Baldwin v. Univ. of Pittsburgh Med. Ctr., 636 F.3d 69, 73 (3d Cir. 2011) ("A dismissal for lack of statutory standing is effectively the same as a dismissal for failure to state a claim."). Although Federal Rule of Civil Procedure 8(a) requires that a complaint contain only "a short and plain statement of the claim showing that the pleader is entitled to relief" to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests," the plaintiff must nonetheless provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (citations omitted). "Factual allegations must be enough to raise a right to relief above the speculative level." Id. Naked assertions devoid of further factual enhancement will not suffice. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Twombly, 550 U.S. at 557).

The Third Circuit has outlined a three-step approach to evaluating whether a complaint satisfies this standard:

> First, the court must "take note of the elements a plaintiff must plead to state a claim." Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." Finally, "where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief."

Schering III, 678 F.3d at 243 (quoting Santiago v. Warminster Twp., 629 F.3d 121, 130 (3d Cir. 2010)) (alterations omitted).

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 556). "While the plausibility standard does not impose a 'probability requirement,' it does demand 'more than a sheer possibility that a defendant has acted unlawfully.'" Schering III, 678 F.3d at 243 (quoting Iqbal, 556 U.S. at 678). The plausibility analysis is "context-specific" and requires a court to draw on "its judicial experience and common sense" to determine if the facts pleaded in the complaint have "nudged" the plaintiff's claims "from conceivable to plausible." Iqbal, 556 U.S. at 679–80.

"With respect to 12(b)(1) motions in particular, '[t]he plaintiff must assert facts that affirmatively and plausibly suggest that the pleader has the right he claims

(here, the right to jurisdiction), rather than facts that are merely consistent with such a right.'" Schering III, 678 F.3d at 244 (quoting Stalley v. Catholic Health Initiatives, 509 F.3d 517, 521 (8th Cir. 2007)).

The Third Circuit has recognized that the injury-in-fact element of constitutional standing, is often determinative. Schering III, 678 F.3d at 245 (quoting Toll Bros., Inc. v. Twp. of Readington, 555 F.3d 131, 138 (3d Cir. 2009)). "'The contours of the injury-in-fact requirement, while not precisely defined, are very generous,' requiring only that [the] claimant 'allege [] some specific, 'identifiable trifle' of injury.'" Danvers Motor Co., Inc. v. Ford Motor Co., 432 F.3d 286, 294 (3d Cir. 2005) (quoting Bowman v. Wilson, 672 F.2d 1145, 1151 (3d Cir. 1982)) (holding that forced expenditures of money and loss of control over business activities are sufficiently concrete forms of injury). Nevertheless, "[a] 'legally and judicially cognizable' injury-in-fact must be 'distinct and palpable,' not 'abstract or conjectural or hypothetical.'" Id. at 291 (quoting Raines v. Byrd, 521 U.S. 811, 819 (1997); Allen v. Wright, 468 U.S. 737, 751 (1984)). Accordingly, "'the standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is

entitled to an adjudication of the particular claims asserted.'" Schering III, 678 F.3d at 245 (quoting Allen, 468 U.S. at 752).

The plaintiffs allege that they suffered economic injury because, absent Cephalon's off-label promotion of Actiq and Fentora, "prescriptions would have issued for alternative drugs which were medically appropriate and less dangerous," and "the medical and prescription drug expenses paid for by Travelers and its customers would have been drastically reduced." Compl. ¶¶ 136-37.

The Amended Complaint suggests two theories of injury: first, that the plaintiffs were injured because they did not get what they paid for (i.e., due to Cephalon's fraudulent off-label promotion, the plaintiffs paid for drugs that were ineffective or unsafe), and second, that the plaintiffs were injured because they paid for more expensive drugs (i.e., but for Cephalon's fraudulent off-label promotion, doctors would have prescribed other less expensive drugs).

As to the first theory, the liberal use of conclusory adjectives such as "ineffective" will not establish standing without factual allegations to show that the plaintiffs themselves were injured by paying for the drugs. For example, the district court in the Schering Plough litigation held that a TPP's complaint did not allege the concrete injury to business

or property required to sustain a RICO claim because it did not contain sufficient allegations that the TPP paid for drugs that were actually ineffective or worth less than the price the TPP paid. See Schering III, 678 F.3d at 246 (discussing the district court's holding in In re Schering Plough Corp. Intron/Temodar Consumer Class Action, No. 06-5774, 2010 WL 2346624, at *4 (D.N.J. June 9, 2010) ("Schering II")).[9]

Here, the plaintiffs claim that they have been injured by paying for Actiq and Fentora, because the drugs were "ineffective" and "unsafe" as prescribed. In support of their assertion that the drugs are ineffective and unsafe, the plaintiffs point to the information contained in the FDA-approved labels and prescribing information, and to FDA-mandated advisory letters stating that the drugs are contraindicated for

[9] Although the Third Circuit agreed with the district court's conclusion in this respect, the Third Circuit did not reach the question of standing under RICO, because the court determined that the plaintiff had not established the prerequisite Article III standing. Schering III, 678 F.3d at 246. On appeal, the TPP stated three distinct injuries: (1) it paid for off-label prescriptions that were ineffective; (2) it paid for off-label prescriptions when less expensive but equally effective medication was available; and (3) it paid for elevated drug prices that recouped the costs of the defendant's illegal marketing. Id. However, because the argument section of the TPP's brief was limited to economic loss based on paying for ineffective drugs, the Third Circuit limited its own analysis to the question of whether the complaint adequately alleged a causal link between the challenged conduct and the alleged injury. Id. at 246-47.

certain uses. In addition, the plaintiffs allege that "[t]o date, Actiq has not been proven to be safe and effective for any purpose other than the treatment of breakthrough cancer pain in opioid-tolerant cancer patients." Compl. ¶ 56.

The absence of data or evidence affirmatively proving that a drug is safe and effective in treating a particular condition, without more, does not support the conclusion that the drug is actually ineffective or unsafe for that use. See, e.g., Schering II, 2010 WL 2346624, at *4 (cautioning that a lack of data amounts only to "an alternative way of expressing that the Defendants had violated the FDCA, as the Subject Drugs' effectiveness for a particular use had not been vetted through FDA approval. The same distinction applies to the Named Plaintiffs claims of safety.").

The plaintiffs rely on three First Circuit decisions in the Neurontin Marketing and Sales Practices multi-district litigation for the proposition that lack of data affirmatively proving effectiveness is sufficient to show ineffectiveness.[10]

[10] Kaiser Found. Health Plan, Inc. v. Pfizer, Inc., 712 F.3d 21 (1st Cir 2013) ("In re Neurontin/Kaiser") (denying defendants' appeal from jury verdict and district court findings, and holding that manufacturer's fraudulent marketing proximately caused injury to TPP); Aetna, Inc. v. Pfizer, Inc., 712 F.3d 51 (1st Cir. 2013) ("In re Neurontin/Aetna") (holding that fact issues precluded summary judgment in defendants' favor on TPP's RICO claim); Harden Mfg. Corp. v. Pfizer, Inc., 712

In In re Neurontin/Kaiser, the First Circuit denied the defendants' appeal from a jury verdict and district court findings in which the district court had allowed the plaintiff to prove its economic injury by showing that there was no reliable scientific evidence that the drug was effective for the off-label conditions at issue.

In In re Neurontin/Kaiser, however, both the jury and the district court had considered the results of numerous double-blind randomized controlled trials and other clinical data indicating that Neurontin was not effective for certain off-label uses, anecdotal accounts of clinical success, regulatory approval in other countries, and expert witnesses and evidence produced by the plaintiffs to show that Neurontin was no more effective than placebo for the off-label uses at issue. The First Circuit held that the totality of the evidence supported the district court's conclusion that the plaintiff had met its burden to show that Neurontin was ineffective. In re Neurontin/Kaiser, 712 F.3d at 32, 47-48.

In this case, by contrast, there are no additional facts alleged in the Amended Complaint supporting the

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F.3d 60 (1st Cir. 2013) ("In re Neurontin/Harden") (reversing grant of summary judgment for defendants on TPP's RICO claim and remanding as to state common law and consumer protection law claims).

plaintiffs' assertion that Actiq and Fentora were ineffective for Travelers' workers' compensation claimants. The plaintiffs do not allege that the drugs failed to relieve any claimant's pain. And none of the strongly worded FDA materials suggest that these drugs do not relieve pain in circumstances for which the drugs have not been approved. In fact, the FDA warnings suggest exactly the opposite, as do any number of the allegations in the Amended Complaint. For example, the plaintiffs repeatedly complain that these drugs were "powerful," "overkill," and "medically unnecessary" for treating the kinds of pain Travelers' claimants suffered. Compl. ¶¶ 34, 35, 92. See also Mot. Hr'g. Tr. 42, Mar. 14, 2014. These factual allegations are inconsistent with the plaintiffs' conclusion that Actiq and Fentora were truly ineffective as prescribed.

The FDA materials do, on the other hand, confirm that both drugs pose substantial risks of severe adverse effects and addiction related to both off-label uses and approved indications. But the plaintiffs do not allege that any Travelers' claimant suffered physical harm as a result of taking Actiq or Fentora, or explain how the mere risk of such harm caused economic injury to the TPPs themselves.

Article III standing requires an invasion of a legally protected interest which is "concrete and particularized" and

"actual or imminent, not conjectural or hypothetical." Lujan, 504 U.S. at 560-61. The fact that a drug poses even a significant possibility of harm does not, by itself, establish injury-in-fact to the party paying for the drug. See, e.g., Rivera v. Wyeth-Ayerst Labs., 283 F.3d 315, 320 (5th Cir. 2002) (patients and TPPs who purchased pain medication that caused liver failure in others did not establish injury-in-fact or causation where medication was not ineffective as to them and did not cause them any physical injury).[11] Because the plaintiffs have not pleaded facts to show that they paid for an ineffective drug, or that the drugs' safety risks resulted in some expenditure by the plaintiffs themselves, the plaintiffs have not pleaded a concrete, particularized injury under their first theory.

Nor is the plaintiffs' second theory of injury – that they paid for more expensive drugs – viable on these alleged

[11] See also In re McNeil Consumer Healthcare Mktg. & Sales Practices Litig., MDL No. 2190, 2011 WL 2802854, at *14-15 (E.D. Pa. July 15, 2011) (mere purchase of defective recalled products is not sufficient to establish economic injury where plaintiffs did not suffer any ill effects from consuming the products). Cf. In re Avandia Mktg., Sales Practices & Prods. Liab. Litig., MDL No. 1871, 2013 WL 3486907, at *3 (E.D. Pa. July 10, 2013) ("Avandia I") (dismissing plaintiff's unjust enrichment claim because "at base Plaintiff alleges that Avandia was not safe, and that GSK knew it was unsafe but promoted the drug anyway, but does not allege that he himself was deprived of the benefit of his bargain").

facts. A plaintiff is not injured simply because it paid for a more expensive drug. If this were so, then any successful marketing campaign – no matter how truthful – that induced a consumer to purchase the more expensive of competing products would cause "economic injury."

In Schering II, for example, the district court explained that the TPP's asserted "overpayment" for drugs based on the existence of cheaper alternatives did not make the subject drugs "inferior or worth less and therefore does not constitute RICO injury." 2010 WL 2346624, at *4.[12] In the Avandia multi-district litigation, by contrast, the district court held that the plaintiffs adequately pleaded economic injury because they alleged specific facts to show that patients would have been prescribed the safer and significantly cheaper competing diabetes drug Metformin, if the defendants had not

[12] See also Ironworkers Local Union 68 v. AstraZeneca Pharm., LP, 634 F.3d 1352, 1360 (11th Cir. 2011) (holding that "the fact that the payer merely paid for more expensive drugs does not suffice" to establish economic injury, unless the drugs were "medically unnecessary or inappropriate according to sound medical practice"); Dist. 1199P Health & Welfare Plan v. Janssen, L.P., 784 F. Supp. 2d 508, 519-20 (D.N.J. 2011) (relying on Maio v. Aetna, 221 F.3d 472, 488 (3d Cir. 2000), in dismissing claims of "overpayment" for off-label prescriptions as insufficient to establish RICO injury, where plaintiffs failed to allege that drug was actually ineffective or worth less than they paid, and plaintiffs' conclusory allegations that other medications were "more effective" or "safer" were unsupported by facts).

suppressed negative data about Avandia's safety. In re Avandia Mktg., Sales Practices & Prods. Liab. Litig., MDL No. 1871, 2013 WL 5761202, at *5 (E.D. Pa. Oct. 23, 2013) ("Avandia II").[13]

Accordingly, a plaintiff cannot simply assert that it was induced to purchase a more expensive drug, but must also plead facts to show that the drug was prescribed or purchased in reliance on untrue statements or misrepresentations about the drug's attributes. In other words, a plaintiff must have paid for something of less value than that which was represented by the defendant. In Avandia, Bextra & Celebrex, and Desiano, for example, the defendants promoted their drugs as safer and/or more effective than cheaper competing products, while actively concealing clinical trial data showing that the drugs were less

[13] See also Desiano v. Warner-Lambert Co., 326 F.3d 339, 342, 349-50 (2nd Cir. 2003) (holding that insurers were directly injured by paying for a drug three times more expensive than standard competing drugs, where the manufacturer falsely advertised the drug as more effective and having "side effects comparable to placebo," in spite of clinical trials showing increased risk of liver injury); In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liab. Litig., No. MDL 05-016999, 2007 WL 2028408, at *5 (N.D. Cal., July 10, 2007) (holding that injury-in-fact is established where the plaintiffs alleged that they would have purchased much less expensive and equally effective over-the-counter painkillers, if the defendants had not falsely marketed their prescription drug as superior).

safe or no more effective. There are no similar allegations here.[14]

First, the plaintiffs in this case have alleged no specific facts to support their assertion that, absent Cephalon's off-label marketing campaign, their medical expenses would have been "drastically reduced." The Amended Complaint does not name any equally effective, safer, less expensive drug that doctors might have prescribed in lieu of Actiq or Fentora. In fact, somewhat paradoxically, the plaintiffs complain that Cephalon reduced the price of Actiq and introduced Fentora at a low price in order to compete with equivalent generic drugs and maintain its market share of the rapid-onset opioid market. Compl. ¶ 114.

More importantly, as discussed in further detail below with regard to their misrepresentation claims, the plaintiffs have not identified any demonstrably false statement or material omission by the defendants about the safety or efficacy of Actiq and Fentora. Because the plaintiffs have not pleaded facts

[14] The plaintiffs cite this Court's decision in In re Wellbutrin XL Antitrust Litig., 260 F.R.D. 143, 156 (E.D. Pa. 2009), for the proposition that reimbursement alone constitutes an "economic injury" to TPP plaintiffs. In Wellbutrin, however, the TPPs alleged that the price of the drugs they paid for was artificially inflated through anticompetitive means. Here, there is no allegation that the prices of Actiq or Fentora themselves were inflated, only that doctors could have prescribed cheaper alternatives.

sufficient to support the allegation that they received a different, less valuable drug than the one described by the defendants – that is to say, the plaintiffs got what they paid for – they have not established a cognizable injury.

C. Motion to Dismiss for Failure to State a Claim Under Federal Rule of Civil Procedure 12(b)(6)

Even assuming the plaintiffs had Article III standing to pursue their claims, the Amended Complaint must also contain factual allegations sufficient to establish each element of their claims.

1. Intentional & Negligent Misrepresentation

Under Connecticut law, a fraud claim is established if "(1) a false representation was made as a statement of fact; (2) the statement was untrue and known to be so by its maker; (3) the statement was made with the intent of inducing reliance thereon; and (4) the other party relied on the statement to his detriment." Weinstein v. Weinstein, 882 A.2d 53, 63 (Conn. 2005). An action for negligent misrepresentation under Connecticut law requires the plaintiff to establish "(1) that the defendant made a misrepresentation of fact (2) that the defendant knew or should have known was false, and (3) that the plaintiff reasonably relied on the misrepresentation, and (4)

suffered pecuniary harm as a result." Nazami v. Patrons Mut. Ins. Co., 910 A.2d 209, 213 (Conn. 2006) (quoting Glazer v. Dress Barn, Inc., 873 A.2d 929, 954 (Conn. 2005)).[15]

[15] The Amended Complaint fails to identify under which state's law the plaintiffs assert their claims for intentional misrepresentation, negligent misrepresentation, unjust enrichment, or mandatory injunction (Counts I-IV). That alone is reason to dismiss these claims. See In re Wellbutrin XL, 260 F.R.D. at 167 ("The plaintiffs fail to link their [unjust enrichment] claim to the law of any particular state. As a result of this deficiency, the plaintiffs fail to state a cause of action . . . .").

The defendants concede that Travelers may have standing under the laws of Connecticut, where Travelers is incorporated, has its principal place of business, and presumably issued reimbursement payments. Travelers, in its opposition briefing, appears to assert that it has standing to bring any of its claims under the laws of thirty-seven different states in which it has claimants, because the alleged wrongdoing took place "throughout the United States." But Travelers has not pleaded facts connecting its alleged economic injuries to a particular state. Accordingly, the Court will look to Connecticut law in considering these claims.

Ultimately, however, this dispute is immaterial to Counts I-IV because the Court finds that the plaintiffs have failed to plead fraud with particularity, and have failed to plead the cognizable injury required to establish these claims in any state. See, e.g., Hunt v. U.S. Tobacco Co., 538 F.3d 217, 225 n.13 (3d Cir. 2008) (quoting Colaizzi v. Beck, 895 A.2d 36, 39 (Pa. Super. Ct. 2006)) (noting that a fraud claim under Pennsylvania law requires plaintiff to show: "'(1) misrepresentation of a material fact; (2) scienter; (3) intention by the declarant to induce action; (4) justifiable reliance by the party defrauded upon the misrepresentation; and (5) damage to the party defrauded as a proximate result'").

The defendants argue that, because the plaintiffs' claims are based entirely on allegations that Cephalon deliberately misrepresented the safety and efficacy of the drugs, their claim for negligent misrepresentation "sounds in fraud." Claims sounding in fraud are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b), which requires that a party "state with particularity the circumstances constituting fraud or mistake," rather than the less stringent requirements of Rule 8(a). See In re Westinghouse Sec. Litig., 90 F.3d 696, 717 (3d Cir. 1996) ("[A]lthough fraud is not a necessary element of a [negligence] claim under section 12(2), section 12(2) claims that do sound in fraud must be pled with particularity."). The Court agrees. The plaintiffs do not allege that Cephalon inadvertently misrepresented Actiq and Fentora as safe and effective for off-label use; instead, throughout the Amended Complaint, they allege that Cephalon's off-label marketing campaign was intentionally deceptive, and deliberately targeted the insurers who would pay for the drugs. Because these allegations sound in fraud, the claims must be pleaded with particularity under the Rule 9(b).

To satisfy Rule 9(b), the plaintiff must "plead or allege the date, time and place of the alleged fraud or

otherwise inject precision or some measure of substantiation into a fraud allegation." Frederico v. Home Depot, 507 F. 3d 188, 200 (3d Cir. 2007). The allegations also must include "who made a misrepresentation to whom and the general content of the misrepresentation." Lum v. Bank of Am., 361 F.3d 217, 224 (3d Cir. 2004).

The plaintiffs contend that they have injected sufficient precision into their fraud allegations by alleging that the fraudulent statements were made by Cephalon's sales representatives, throughout the United States, from October 2000 to the present. But allegations that at some point in the last thirteen years unidentified members of the defendants' sales team made unspecified false statements or misrepresentations about Actiq or Fentora to unidentified doctors somewhere in the United States are insufficient under even a generous construction of Rule 9(b).

Moreover, despite the liberal use of the words "fraudulent," "deceptive," and "misleading" in describing the defendants' marketing efforts, the Amended Complaint fails to identify a single false statement, misrepresentation, or deliberate material omission by the defendants. The gist of the plaintiffs' argument, as articulated at the March 14, 2014 hearing on this motion, appears to be that, because Actiq and

Fentora have not been proven safe or effective for any off-label use, any off-label promotion is, ipso facto, "fraudulent." Hr'g Tr. 33, 35.[16] The Court does not agree with this conclusion. Courts consistently have held that off-label promotion is not inherently deceptive, and does not support a private action for fraud or negligent misrepresentation unless the promotion includes an untruthful or misleading statement about the safety or efficacy of the drug itself. See, e.g., Cent. Reg'l Emps. Benefit Fund v. Cephalon, Inc., No. 09-3418, 2009 WL 3245485, at *4 (D.N.J. Oct. 7, 2009) ("Merely alleging that Cephalon marketed the drugs at issue for off-label purposes does not state a claim for fraud.").[17]

[16] In support of this proposition, the plaintiffs rely on U.S. ex rel. Galmines v. Novartis Pharm. Corp., No. 06-3213, 2013 WL 2649704 (E.D. Pa. June 13, 2013), which appears to suggest that defendants can commit fraud merely by promoting a drug for a contraindicated use. But Galmines was a False Claims Act case in which the alleged fraud consisted of the submission of off-label prescriptions to the government for reimbursement, where it was also alleged that the government program did not cover off-label prescriptions. Under those particular circumstances, even truthful off-label promotion might have led to the submission of a fraudulent claim to the government.

[17] See also Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc., No. 13-7167, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) (Bartle, J.) ("[W]hile Cephalon's actions may well constitute improper off-label promotion under the FDCA and its regulations, . . . it does not follow that the promotion is fraudulent."); In re Actimmune Mktg. Litig., 614 F. Supp. 2d 1037, 1051 (N.D. Cal. 2009) ("Actimmune I") (explaining that plaintiffs' allegations incorrectly "conflate a false and

Despite the plaintiffs' contention that Cephalon engaged in this wide-reaching, highly effective fraudulent marketing campaign for more than a decade, the Amended Complaint itself refers to very few specific communications by the defendants regarding off-label use of Actiq and Fentora. With regard to communications directed at prescribing physicians, the Amended Complaint names one internal promotional document titled "Actiq for Migraine." Compl. ¶ 78.[18] The Amended Complaint also describes the contents of an educational seminar titled "Breakthrough Pain: Improving Recognition and Management to Enhance Quality of Life," which was sponsored by Cephalon in 2008-2009. The seminar materials discuss "overestimation of opioid risks" and "regulatory and liability concerns," recommend treating breakthrough pain with a short-acting opioid, and conclude that "fentanyl is better suited than slower-acting

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misleading statement under the FDCA, i.e., one that occurs when the drug label does not match the promoted assertion about the drug, and a false and misleading statement *about the drug itself*") (emphasis in original).

[18] The plaintiffs also allege that Cephalon trained its sales staff to make false or misleading statements to physicians about Actiq and Fentora, to use non-FDA-approved marketing materials to promote off-label uses, and to provide doctors with dosage recommendations that were inconsistent with FDA-approved guidelines. But (with the exception of the title of the "Actiq for Migraine" document) the contents of these statements and materials are not described in the Amended Complaint, nor does the Amended Complaint specify when, where, or to whom any sales pitch was made.

agents" for managing certain types of breakthrough pain. Compl. ¶¶ 142-47. But communications discussing, or even encouraging, non-FDA-approved uses are not inherently fraudulent, and the plaintiffs have not explained in what way the statements above are deceptive or misleading. See Carpenters Welfare Fund, 2014 WL 2115498, at *5 ("A topic on the 'overestimation' of risks could imply that the Defendants covered up Fentora's dangers, but it is equally consonant with an honest discussion on weighing the merits and demerits of opioid medications.").[19]

The Amended Complaint also expounds on Cephalon's statements to investors regarding its plans to promote Fentora to certain physicians, to reduce the prices of Actiq and Fentora to maintain market share, to focus on "positive messages around Fentora" in response to the FDA's Healthcare Advisory Warnings in 2007, to study off-label uses of Fentora, and to seek expanded FDA approval based on positive trial results for off-label use by opioid-tolerant patients with chronic back pain.

[19] See also In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig., No. MDL 08-1934, 2009 WL 1703285, at *6 (C.D. Cal. June 17, 2009) (". . . Plaintiffs must show that [Defendant]'s actions went beyond presenting its drugs in the best light possible and crossed the line into actionable fraud. . . . [I]f [Defendant] had falsely represented in its informational materials that [the drug] was FDA-approved for an off-label use, such conduct would almost certainly be fraudulent. Similarly, if . . . [Defendant] made untrue statements about the results of a particular study, this would likely support a fraud-based . . . claim.").

Compl. ¶¶ 114-128. Although these statements reflect Cephalon's desire to expand off-label use of Fentora, they do not convey any false or deceptive information.[20]

With regard to the plaintiffs' allegation that the defendants' marketing omitted or negated unfavorable information about the drugs, the Amended Complaint does not plead any particularized facts. The contraindication warnings are prominent in all the FDA materials and the drug labels, including the Black Box warning on the Fentora label, and were additionally highlighted in FDA-mandated advisory letters Cephalon sent to prescribing doctors in 2007. Compl. ¶ 123. Even accounting for Cephalon's aggressive positive marketing of Actiq and Fentora for off-label use, no facts alleged in the Amended Complaint suggest that Cephalon concealed or misrepresented the content of the FDA materials to prescribing physicians, sophisticated consumers who themselves have an affirmative duty to be familiar with them. See, e.g., Actimmune I, 614 F. Supp. 2d at 1054-55 ("Plaintiffs make tendentious leaps in concluding that defendants['] marketing efforts are false and misleading simply because defendants presented their

[20] Judge Bartle's recent opinion in Carpenters Welfare Fund also notes that statements made to financial analysts that were not made to potential Fentora prescribers, patients, or payors, "cannot reasonably serve as the basis of a claim for fraudulent marketing activity." 2014 WL 2115498 at *6 n.3.

drug product in the best light possible. . . . There is a clear distinction in the law between puffery and fraud.").[21]

Implicit in the plaintiffs' argument is the suggestion that Cephalon must have misrepresented the safety or efficacy of the drugs, or doctors would not have prescribed them for off-label use. But the limited factual allegations in the Amended Complaint do not support this conclusion, and the mere possibility that such misrepresentation occurred is insufficient to state a claim for fraud. See, e.g., In re Actimmune Mktg. Litig., No. C 08-02376, 2009 WL 3740648, at *11 (N.D. Cal. Nov. 6, 2009) ("Actimmune II") ("[A] claim that an individual was 'likely' exposed to fraudulent conduct and 'likely' relied upon that conduct to their detriment cannot satisfy Rule 9(b).").

Recently, addressing a TPP's RICO claims against Cephalon based on its off-label promotion of Fentora, Judge Bartle cautioned that, even if Cephalon's corporate culture was shown to be "contemptuous of the FDA rules on marketing and promotion," a court does not have license to interpret the

[21] See also id. at 1054 ("[C]ourts have routinely refused to find promotional marketing of off-label uses fraudulent when they are directed at sophisticated audiences, like physicians."); United States v. Caronia, 576 F. Supp. 2d 385, 397-98 (E.D.N.Y. 2008) (declining to find speech inherently misleading when directed at physicians, "who are familiar with the FDA-approval process and able to independently evaluate the validity of their claims").

company's actions as fraudulent when the plaintiff has not met the pleading mandate of Rule 9(b). Carpenters Welfare Fund, 2014 WL 2115498, at *7. Reiterating that it is not illegal for physicians to prescribe Fentora for off-label use, Judge Bartle held that, "[u]nder the circumstances, it is simply insufficient to allege off-label promotion . . . without describing the 'who, what, when, where and how' of any scheme to defraud as that term is defined by federal law, or without providing the necessary precision or substantiation that would otherwise excuse a failure to plead the date, place, or time of the alleged fraud." Id. at *7 (citing In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002); Lum, 361 F.3d at 224). The Court agrees.

Here, the facts pleaded by the plaintiffs show no more than Cephalon's off-label promotion of Actiq and Fentora, which does not by itself state a claim for fraud or misrepresentation. These allegations do not satisfy the less exacting pleading requirements of Rule 8(a), much less the heightened standard of Rule 9(b).

2. State Unfair Competition Laws

Without detailing the elements of any state's consumer protection statute, the plaintiffs allege that Cephalon's off-

label marketing of Actiq and Fentora to "consumers or the general public" constituted "unfair or deceptive acts or practices" in violation of the laws of Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Hawaii, Idaho, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Virginia, and Wisconsin.

Travelers is located in Connecticut, and the defendants concede that the plaintiffs have standing under Connecticut's consumer protection law, but challenge their standing to assert claims under any state law. Relying on this Court's Wellbutrin decision, the plaintiffs assert that they have standing to sue under the consumer protection laws of any state in which Travelers' insureds are located.[22] But they have failed to allege in which state or states any claimant filled a

[22] In Wellbutrin, this Court concluded that the plaintiff benefit funds might bring claims under the laws of the states in which they were located or in which resided any member for whom they had reimbursed purchases of Wellbutrin XL. In re Wellbutrin XL, 260 F.R.D. at 167. But see Avandia II, 2013 WL 5761202, at *9-10 (holding that TPPs have standing to sue only under the consumer protection acts of the state in which the TPP itself is located).

prescription for Actiq or Fentora, or how the plaintiffs themselves suffered economic injury in any particular state.

Connecticut's Unfair Trade Practices Act ("CUTPA"), Conn. Gen. Stat. Ann. §§ 42-110a, et seq., provides a private cause of action to "[a]ny person who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment of a [prohibited] method, act or practice." Nazami, 910 A.2d at 213 (quoting Fink v. Golenbock, 680 A.2d 1243, 1259 (Conn. 1996); Conn. Gen. Stat. Ann. § 42-110g(a)) (quotation marks omitted).

The plaintiffs point out that many state consumer protection statutes, including Connecticut's, prohibit not only fraudulent or deceptive acts, but also sales practices that are "unfair" or against public policy. Moreover, many do not require first-party reliance on the alleged misrepresentation to establish causation, and do not require a plaintiff to plead with the particularity required by Rule 9(b). Nevertheless, state consumer protection statutes do require that a plaintiff have suffered an ascertainable loss or injury as a result of a defendant's alleged wrongdoing.[23] Because the Court has found

[23] See, e.g., Hunt, 538 F.3d at 221 n.3 (noting that a private right of action may be brought by "'[a]ny person who . . . *suffers any ascertainable loss* of money or property, real or personal, *as a result of the use or employment by any person of*

that the plaintiffs have failed to plead a cognizable injury sufficient to establish Article III standing, the plaintiffs' state consumer protection claims must also fail.

3. Unjust Enrichment

Under Connecticut law, "'[p]laintiffs seeking recovery for unjust enrichment must prove (1) that the defendants were benefited, (2) that the defendants unjustly did not pay the plaintiffs for the benefits, and (3) that the failure of payment was to the plaintiffs' detriment. . . . The question is: Did [the party liable], to the detriment of someone else, obtain something of value to which [the party liable] was not entitled?'" Schirmer v. Souza, 12 A.3d 1048, 1052 (Conn. App.

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a[n] [unlawful] method, act, or practice . . . .'") (quoting 73 Pa. Cons. Stat. § 201-9.2) (emphasis in original). Even if this Court were to decide that the defendants' actions – though not fraudulent – were unfair or against public policy, the plaintiffs would nevertheless have to plead both injury and causation, including justifiable reliance on some communication by the defendants. See, e.g., Hunt, 538 F.3d at 222 (observing that the Supreme Court of Pennsylvania has "consistently interpreted [Pennsylvania's Unfair Trade Practices and] Consumer Protection Law's private-plaintiff standing provision's causation requirement to demand a showing of justifiable reliance, not simply a causal connection between the misrepresentation and the harm."). Inasmuch as the plaintiffs have failed to plead that any particular doctor heard or believed the defendants' statements and relied on those statements in deciding to prescribe Actiq or Fentora, plaintiffs have not pleaded causation.

Ct. 2011) (quoting New Hartford v. Conn. Resources Recovery Auth., 970 A.2d 592, 609-10 (Conn. 2009)).[24]

The defendants argue that, having failed to state a claim for fraud or misrepresentation, the plaintiffs have not established how it would be unjust or inequitable for the defendants to retain the money paid for off-label Actiq and Fentora prescriptions. See Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 936–37 (3d Cir. 1999). The defendants also argue that the unjust enrichment claim fails because Actiq and Fentora were, in fact, effective in relieving pain, and did not cause injury to their members. In other words, the plaintiffs received the benefit of their bargain, and the defendants were not unjustly enriched in retaining payment for the drugs. See Avandia II, 2013 WL 5761202, at *11. The plaintiffs contend that, even if they received some value for their money, the benefit conferred on the defendants stemmed from their wrongdoing, and it is therefore unjust to allow them to retain it. See In re K-Dur

[24] Similarly, under Pennsylvania law, "[t]o make out a claim for unjust enrichment, a plaintiff must establish 'benefits conferred on defendant by plaintiff, appreciation of such benefits by defendant, and acceptance and retention of such benefits under such circumstances that it would be inequitable for defendant to retain the benefit without payment of value.'" Piper v. Portnoff Law Assocs., 216 F.R.D. 325, 329 n.9 (E.D. Pa. 2003) (quoting Schenck v. K.E. David, Ltd., 666 A. 2d 327, 328–29 (Pa. Super. Ct. 1995)).

Antitrust Litig., 338 F. Supp. 2d 517, 545 (D.N.J. 2004) (holding that plaintiffs' receipt of medicine of some value did not bar an unjust enrichment claim).[25]

Here, the Court has found that the plaintiffs have failed to plead either cognizable injury to themselves or fraudulent conduct by the defendants. In light of these pleading deficiencies, the plaintiffs have not established circumstances under which "the party liable, to the detriment of someone else, obtain[ed] something of value to which the party liable was not entitled," Schirmer, 12 A.3d at 1052 (internal punctuation omitted). The plaintiffs' claim for unjust enrichment is therefore dismissed.[26]

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[25] The parties also dispute whether unjust enrichment is a stand-alone claim that could survive a motion to dismiss even if the plaintiffs' other claims fail. Addressing an unjust enrichment claim against Cephalon under Indiana law, Judge Bartle recently held that such a claim is its own cause of action, with its own required elements. Carpenters Welfare Fund, 2014 WL 2115498, at *10 (citing In re Actiq Sales & Mktg. Practices Litig., 790 F. Supp. 2d 313, 329 n.17 (E.D. Pa. 2011) (declining to dismiss unjust enrichment claims where the plaintiffs' state consumer protection claims survived summary judgment)). Because the Court finds that the plaintiffs have failed to plead the elements necessary to establish that the defendants were unjustly enriched, the Court does not address this question here.

[26] See also Carpenters Welfare Fund, 2014 WL 2115498, at *10 (finding no authority for the proposition that payment for a drug that has been promoted off-label, without more, presents the sort of circumstances which mandate restitution, and holding that, where there are no well-pleaded allegations of fraudulent

4. Request for Mandatory Injunction

In addition to their claims for damages resulting from fraud and negligent misrepresentation, the plaintiffs seek a mandatory injunction requiring Cephalon to take steps to correct any misunderstanding prescribing doctors may have about the safety or efficacy of Actiq and Fentora for off-label use.

The defendants argue that this claim must be dismissed because an injunction is a form of relief, rather than a separate cause of action. Although the plaintiffs assert several times in their Opposition memorandum that their allegations are sufficient to support their claim for injunctive relief, they do not address until their Sur-reply memorandum whether a request for injunction is a viable free-standing claim. Therefore, the defendants contend, the plaintiffs have waived their objection to that argument.[27]

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conduct or averments that patients did not enjoy the clinical benefits of the prescriptions, there is insufficient substantive basis for an unjust enrichment claim).

[27] Some state courts, including the Connecticut Superior Court, recognize a claim for an injunction as a stand-alone cause of action. See, e.g., Baker v. Town of Cheshire, 45 Conn. L. Rptr. 452, 2008 WL 1971495, at *9 (Conn. Super. Ct. Apr. 24, 2008) ("It appears that a majority of Connecticut courts have recognized a claim for an injunction as a viable free-standing cause of action."). See also Rainone v. Bank of America, 2013

Even assuming the plaintiffs have not waived this argument, and assuming that the governing state law recognizes such a claim as a separate cause of action, a party seeking an injunction under Connecticut law "has the burden of alleging and proving irreparable harm and lack of an adequate remedy at law." Johnson v. Statewide Grievance Comm., 726 A.2d 1154, 1164 (Conn. 1999) (quotation and emphasis omitted). Because the plaintiffs have failed to allege facts to support the conclusion that they have suffered or may imminently suffer any irreparable injury as a result of the defendants' conduct, their fourth cause of action is dismissed.[28]

5. Claims Against Teva USA and Teva Ltd.

Finally, the plaintiffs seek to hold Teva USA and Teva Ltd. liable because these companies' websites state that Actiq and Fentora are two of the companies' global brands, and the companies have benefitted from the increased sales of the two drugs. Compl. ¶¶ 148-55. Based on these facts alone, the plaintiffs assert that Teva USA and Teva Ltd. must be aware of

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WL 5879009, at *2-3 (Conn. Super. Oct. 11, 2013) (analyzing plaintiff's request for injunctive relief as a separate claim).

[28] To the extent that the defendants have, in fact, failed to conform to the requirements of the RPM, corrective action may be ordered by the FDA, but such failure does not support a private right of action or establish harm to the plaintiffs. Hr'g Tr. 37.

Cephalon's fraudulent off-label promotion, have failed to correct it, and have benefitted as a result of the alleged wrongdoing. But a parent company is not liable for the actions of its subsidiaries unless the parent company itself has engaged in wrongdoing, or exercises control over the subsidiary entity. In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 341 n.44 (3d Cir. 2010) (citing 1 William Meade Fletcher, Cyclopedia of Law of Private Corporations § 33, at 89 (perm. ed. rev. vol. 2006)). The fact that Teva USA and Teva Ltd. may have profited from sales of Actiq and Fentora is simply insufficient to establish either control of Cephalon's activities or actual wrongdoing by these corporate entities.

III. Conclusion

For the reasons explained above, the motion to dismiss is granted.

An appropriate Order shall issue.